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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/843,676	04/26/2001	Thomas R. Cech	15389002943	9640

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EXAMINER	
WALICKA, MALGORZATA A	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/843,676	Applicant(s) CECH ET AL.	
	Examiner Malgorzata A. Walicka	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-32* is/are pending in the application.

4a) Of the above claim(s) *27,28,31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-26,29 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *10* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Preliminary Amendment filed on Dec. 17, 2001 as paper No. 9 is acknowledged. Amendment to the claims has been entered as requested. Claims 1-20 are cancelled. New claims 21-32 are entered. Claims 21-32 are pending and are the subject of this Office Action.

DETAILED ACTION

1. Restriction/election

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 21-26 and 29-30 drawn to polypeptide comprising fragments of SEQ ID NO: 225 and products thereof, classified in class 530, subclass 350.

II. Claim 27-28, 31-32, drawn to a method of eliciting an immune response to telomerase reverse transcriptase, classified in class 424, subclass 185.1.

Inventions of Group I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product, the polypeptide comprising fragments of the human telomerase may be used in the method of identification of modulators of its activity and not for eliciting an immune response to telomerase.

Inventions of Group I-II are distinct for the reasons given above and have acquired a separate status in the art. Because of their recognized divergent subject matter and/or different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

During a telephone conversation with Applicant representative Scott Ausenhus on November 17, 2003, a provisional election was made without traverse to prosecute the invention of Group I, claims 21-26 and 29-30. Affirmation of this election must be made by Applicant in replying to this Office Action.

Claims 27-28, 31-32 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

2. Objections

2.12. Specification

A substitute specification is required under 37 CFR 1.125(a) because the Preliminary Amendment filed August 16, 2001 consisting of a lengthy (19 pages) amendment to the specification has not been entered.

A substitute specification filed under 37 CFR 1.125(a) must only contain subject matter from the original specification and any previously entered amendment under 37 CFR 1.121. If the substitute specification contains additional subject matter not of record, the substitute specification must be filed under 37 CFR 1.125(b) and (c)

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors in the specification of which applicant may become aware.

3. Rejections

3.1. 35 USC, section 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3.1.1. Lack of written description

Claims 21-26 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a large and variable genus of polypeptides comprising (the language "consisting essentially of" in claims 29 and 30 has the meaning "comprising") at least 5 amino acid fragment of SEQ ID NO: 225. The structures and functions of the species of said genus that includes any man-made and natural polypeptides, including other than SEQ ID NO: 225 splice variants of human telomerase, are not stated by the claims. The specification teaches only one representative species by identifying its structure, SEQ ID NO: 225, and function, i.e. telomerase reverse transcriptase. The specification provides also structural description of several species of the genus, SEQ ID Nos: 112-117 and SEQ ID NOs: 71, 73, 75, 77, 79, 82, 83, 84, 85, 87, 101, and 174-223. The functions of polypeptides having the identified structures are not taught by Applicants. Thus, the teachings of the specification and claims are insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Applicants fail to disclose any particular structure to function/activity for polypeptide of SEQ ID NO: 225, so that one skilled in the art could recognize the polypeptide comprising at least 5-10 amino acid fragment of SEQ ID NO: 225 retains the desired telomerase function. In addition, claim 23 is directed to the subgenus of the polypeptides that lost the telomerase function, but their new function, if any, is not identified.

In conclusion, given the lack of structural and functional characteristics of additional representative species as encompassed by the claim, Applicants failed to

sufficiently describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention when the application was filed.

Limiting the claims to polypeptides consisting of fragments of SEQ ID NO: 225 having function of use in production of antibody against telomerase would overcome this rejection.

3.1.2. Scope of enablement

Claim 21-26 and 29-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 225 or fragments thereof consisting of at least 10 consecutive aminoacids, does not reasonably provide enablement for any polypeptide containing at least 5-10 consecutive amino acids of SEQ ID NO: 225 and compositions thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The scope of the claims covers an extremely large and variable genus of polypeptides with little structural similarity to SEQ ID NO: 225, and with no stated function, for which the guidance in the specification is clearly lacking. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Otherwise, undue experimentation is necessary to make the claimed invention.

Factors to be considered in determining whether undue experimentation is required are summarized *In re* Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and scope of invention encompass an extremely large genus of polypeptides comprising at least 5-10 amino acid fragments of SEQ ID No: 225, said genus has no function and includes any man-made and natural polypeptides.

While methods of protein structure and function manipulations are well known in the relevant art, and skills of the artisans highly developed, the probability of success in obtaining the claimed invention is very low due to the lack of functional and structural characteristics of claimed polypeptides.

While enablement is not precluded by the necessity for routine screening and/or molecule modification, if a large amount of screening and molecular engineering is required, the specification must provide a reasonable amount of guidance with respect to the direction in which the experimentation should proceed so that the claimed species have the desired functionality. The structural provision of human telomerase of SEQ ID NO: 225 fails to provide such guidance of polypeptides with any function and major structural variations from SEQ ID NO: 225 that remain encompassed within the scope of the rejected claims.

In conclusion, without a further guidance on the part of Applicants with regards to the structure and function of the claimed inventions experimentation left to those in the art is improperly extensive and undue.

3.2. Nonstatutory Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 21-22, 24-26 and 29-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,261,836 B1(enclosed in the Information Disclosure Statement). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application as generic claims would be anticipated by claim 1 of the patent. An obviousness–type double patenting is appropriate where the conflicting claims are not identical, but an examined claim is either anticipated by, or would have been obvious over the reference claim (s). See e.g. *In re Berg*, 140 F.3d 1428, 46USPQ2d1226 (Fed.Cir. 1998); *In re Boodman*, 11F.3 d 1046, 29USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F. 2d 887, 225 USPO 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 21-22, 24-26 and 29-30 of the application are generic to all that is recited in claim 1 of U.S. Patent No. 6,261,836 B1. That is, claim 1 of the patent falls entirely within the scope of claims 21-22, 24-26 and 29-30 or, in other words, claim 21-22, 24-26 and 29-30 13 are anticipated by claim 1 of the patent. Specifically, the polypeptide of claim 1 of the patent is subgenus of the genus of polypeptides of claims 21-22, 24-26 and 29-30 of the application.

In addition, claims 21-22, 24-26 and 29-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending applications No. 09/766,253 and No. 09/438,486. Although the conflicting claims are not identical, they are not patentably distinct from each other

because claim 1 of the enumerated applications is directed to polypeptides comprising the following fragments of SEQ ID NO: 225: SEQ ID NO: NOs: 71, 73, 75, 77, 79, 82, 83, 84, 85, 87, 101. SEQ ID NOs: 71, 73, 75, 77, 79, 82, 83, 84, 85, 87, 101 are at least 5 amino acid fragments of SEQ ID NO: 5 thus they are species of the genus claimed in claims 21-26 and 29-30 of the examined application. Claims 1 of the enumerated applications falls entirely within the scope of claims 21-26 and 29-30 of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Furthermore, claims 21-26 and 29-30 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1-3, 6-8 and 10 of copending Application No. 10/044,692. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1-3, 6-8 and 10 of the Application No. 10/044,692 are directed to polypeptides comprising the following at least 8 amino acid fragments of SEQ ID NO: 2 of the Application No. 10/044,692 which is identical to SEQ ID NO: 225 of the instant application. Thus the scope of claim 1-3, 6-8 and 10 of copending Application No. 10/044,692 is encompassed in the scope of claims 21-26 and 29-30, or in another words, claims of the application No. 10/044,692 are directed to subgenus of the genus claimed in claims 21-26 and 29-30 of the examined application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Conclusion

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Malgorzata A. Walicka, Ph.D., whose telephone number is (703) 305-7270. The examiner can normally be reached Monday-Friday from 10:00 a.m. to 4:30 p.m.

If attempts to reach examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, Ph.D. can be reached on (703) 308-3804. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionists whose telephone number is (703) 308-0196.

Malgorzata A. Walicka, Ph.D.
Patent Examiner
Art Unit 1652

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